APR 6 2006

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K060650

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3143

Contact Person: Michael M. Byrne

2. **Preparation date**

Date Special 510(k) prepared: March 10, 2006

3. **Device name**

Trade or Proprietary Name:
VITROS Chemistry Products d%A1c Reagent Kit
VITROS Chemistry Products Calibrator Kit 18
VITROS Chemistry Products FS Calibrator 1
Common Name : Glycohemoglobin assay
Classification Name: Glycosylated hemoglobin assay (21 CFR 864.7470).

4. **Predicate device**

The VITROS Chemistry Products d%A1c Reagent Kit (modified),VITROS Chemistry Products Calibrator Kit 18 and VITROS Chemistry Products FS Calibrator 1 are substantially equivalent to VITROS Chemistry Products %A1c Reagent Kit (current), VITROS Chemistry Products Calibrator Kit 18, and VITROS FS Calibrator 1 which were cleared by the FDA for in vitro diagnostic use.

VITROS %A1c Reagent Kit: (K041764, Cleared September 9, 2004)
VITROS Calibrator Kit 18: (K041764, Cleared September 9, 2004)
VITROS FS Calibrator 1: (K052645, Cleared December 14, 2005).

5. Device description

1. VITROS Chemistry Products d%A1c Reagent Kit, VITROS Chemistry Products Calibrator Kit 18, and VITROS Chemistry Products FS Calibrator 1 are combined with the VITROS 5,1 FS Chemistry System to perform the VITROS d%A1c assay.
    a. **VITROS d%A1c Reagent Kit** contains two unique dual chambered reagent packs containing ready to use liquid reagents that are used to measure both hemoglobin A1c (HbA1c) and hemoglobin (Hb).
        i. Hemoglobin A1c Reagent Pack (HbA1c)
            1. The R1 chamber (HbA1c Reagent 1) consists of:
                a. HbA1c antibody (ovine serum)
                b. Buffers
                c. Stabilizers
                d. Preservatives
            2. The R2 chamber (HbA1c Reagent 2) consists of:
                a. HbA1c Polyhapten
                b. Buffers
                c. Stabilizers
                d. Preservatives
        ii. Hemoglobin Reagent Pack (Hb)
            1. The R1 chamber (Hb Reagent 1) consists of:
                a. Buffer
                b. Stabilizers
                c. Preservatives
            2. The R2 chamber (Hb Reagent 2) contains Hemolyzing Reagent, which consists of:
                a. Tetradecyltrimethylammonium bromide (TTAB) <1% (w/v)
                b. Water
    b. **VITROS Chemistry Products Calibrator Kit 18** is composed of a hemolysate derived from human and ovine blood to which surfactants, stabilizer, and preservative have been added. This lyophilized calibrator is reconstituted with VITROS Chemistry Products FS Reconstitution Diluent, which is composed of processed water.
    c. **VITROS Chemistry Products FS Calibrator 1** is composed of processed water and 0.9% w/v sodium chloride (saline).

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5. Device description (con't)

2. The VITROS d%A1c assay is designed to use whole blood to determine %A1c on-board the VITROS 5,1 FS System without the need for sample pretreatment.
3. The determination of percent glycated hemoglobin (%A1c) is performed using the VITROS d%A1c Reagent Kit in conjunction with VITROS Calibrator Kit 18 and VITROS FS Calibrator 1 on the VITROS 5,1 FS Chemistry System. The VITROS d%A1c Reagents consists of two unique dual chambered packs containing complete ready-to-use liquid reagents. Whole blood samples are hemolyzed on the VITROS 5,1 FS Chemistry System during the sample analysis. Since this is a direct reacting assay, no sample pretreatment by the operator is required to perform this assay.

The VITROS 5,1 FS Chemistry System is designed specifically for use with the VITROS Chemistry Products range of products.

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6. Device intended use

VITROS Chemistry Products d%A1c Reagent Kit: For *in vitro* diagnostic use only. VITROS Chemistry Products d%A1c Reagent is used to determine the percent glycated hemoglobin (%A1c) in human whole blood by quantitative measurement of hemoglobin (Hb) and hemoglobin A1c (HbA1c). Measurements of percentage A1c are effective in monitoring long-term glycemic control in individuals with diabetes mellitus.

VITROS Chemistry Products Calibrator Kit 18: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 18 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the calculation of percent glycated hemoglobin (%A1c).

VITROS Chemistry Products FS Calibrator 1: For *in vitro* diagnostic use only. VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits 16, 17, 18, 19 and 28 to calibrate VITROS 5,1 FS Chemistry Systems.

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7. Comparison to predicate device

The VITROS Chemistry Products d%A1c Reagent Kit (modified),VITROS Chemistry Products Calibrator Kit 18 and VITROS Chemistry Products FS Calibrator 1 are substantially equivalent to VITROS Chemistry Products %A1c Reagent Kit (current), VITROS Chemistry Products Calibrator Kit 18, and VITROS FS Calibrator 1 which were cleared by the FDA for in vitro diagnostic use.
VITROS %A1c Reagent Kit: (K041764, Cleared September 9, 2004)
VITROS Calibrator Kit 18: (K041764, Cleared September 9, 2004)
VITROS FS Calibrator 1: (K052645, Cleared December 14, 2005).

Table 1 lists the characteristics of the tests performed using the VITROS d%A1c Reagent Kit (modified) and the VITROS %A1c Reagent Kit (current).

Table 1 List of Reagent Characteristics: Comparison to Predicate Device

Comparison to predicate device: Reagent Kit		
	New device (modified)	**Predicate device (current)**
Device Characteristics	**VITROS Chemistry Products d%A1c Reagent Kit**	**VITROS Chemistry Products %A1c Reagent Kit**
Specimen Hemolysis	Specimen hemolysis to be performed as an automated step by the VITROS 5,1 FS Chemistry System using VITROS Chemistry Products Hemolyzing Reagent, which has been placed in the R2 chamber of the VITROS Hb Reagent Pack.	Pretreatment step performed by manually adding 1 part sample to 100 parts VITROS Chemistry Products Hemolyzing Reagent prior to analysis.
Intended Use	For *in vitro* diagnostic use only. VITROS Chemistry Products d%A1c Reagent Kit is used to determine the percent glycated hemoglobin (%A1c) in human whole blood by quantitative measurement of hemoglobin (Hb) and hemoglobin A1c (HbA1c). Measurements of percentage A1c are effective in monitoring long-term glycemic control in individuals with diabetes mellitus.	For *in vitro* diagnostic use only. VITROS Chemistry Products %A1c Reagent Kit is used to calculate percent glycated hemoglobin (%A1c) in pretreated human whole blood by quantitative measurement of hemoglobin (Hb) and hemoglobin A1c (HbA1c). Measurements of percentage A1c are effective in monitoring long-term glucose control in individuals with diabetes mellitus..
Sample Type	Whole Blood (EDTA)	Whole Blood (EDTA, Heparin, sodium fluoride, potassium oxalate)
Standardization	No change expected, NGSP certification testing is currently in progress.	Traceable to the Diabetes Control and Complications Trial (DCCT) and IFCC reference methods. Certified by the National Glycohemoglobin Standardization Program (NGSP)
Basic Principle	No Change	Turbidimetric inhibition immunoassay
Reportable Range	No Change	4-14 %A1c NGSP
Reagents	No Change	Liquid ready to use
Instrumentation	No Change	VITROS 5,1 FS Chemistry System

8. Conclusions

The information presented in this pre-market notification demonstrates that the performance of the VITROS Chemistry Products d%A1c Reagent for use with human whole blood is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured reagents along with patient and quality control samples with measured %A1c values spanning the reportable range.

The information presented in this premarket notification provides a reasonable assurance that the VITROS Chemistry Products d%A1c assay for use with human whole blood is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 6 2006

Mr. Michael M. Byrne
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k060650
Trade/Device Name: VITROS Chemistry Products d%A1c Reagent Kit
VITROS Chemistry Products Calibrator Kit 18
VITROS Chemistry Products FS Calibrator 1
Regulation Number: 21 CFR§864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, JIT
Dated: March 10, 2006
Received: March 13, 2006

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060650

Device Name: VITROS Chemistry Products d%A1c Reagent Kit
VITROS Chemistry Products Calibrator Kit 18
VITROS Chemistry Products FS Calibrator 1

Indications for Use: For *in vitro* diagnostic use only.
VITROS Chemistry Products d%A1c Reagent Kit is used to determine the percent glycated hemoglobin (%A1c) in human whole blood by quantitative measurement of hemoglobin (Hb) and hemoglobin A1c (HbA1c). Measurements of percentage A1c are effective in monitoring long-term glycemic control in individuals with diabetes mellitus.

For *in vitro* diagnostic use only.
VITROS Chemistry Products Calibrator Kit 18 is used in conjunction with VITROS Chemistry Products FS Calibrator 1 to calibrate VITROS 5,1 FS Chemistry Systems for the calculation of percent glycated hemoglobin (%A1c).

For *in vitro* diagnostic use only.
VITROS Chemistry Products FS Calibrator 1 is used in conjunction with VITROS Chemistry Products Calibrator Kits 16, 17, 18, 19 and 28 to calibrate VITROS 5,1 FS Chemistry Systems.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060650